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510(k) Summary of Safety and Effectiveness
MedChannel Endoscopic Accessories
Monday, May 23, 2005

Company Name

MedChannel, LLC
75 Federal Street, 9th Floor
Boston, MA 02210

Official Contact

Frederick Tobia
Regulatory Consultant

Device Name

Proprietary Name:	MedChannel OptiCLEAN Lens Irrigator & OptiDOCK Tissue Ligator
Common Name:	Endoscopic Lens Irrigator/Cleaner Endoscopic Suture Passer
Classification Name(s):	21 CFR § 876.1500 Endoscope and Accessories 21 CFR § 878.4493 Suture, absorbable, synthetic

Predicate Devices used for Substantial Equivalence

Endoscopic Anti Fog Device	Mectra Labs
Endoscopic Irrigation Channel	Byrne Medical
Endosuture Suture Passer	Ethicon
Surgisorb Absorbable Suture	Samyang Corporation

Intended Use & Indications

The OptiCLEAN Lens Irrigator is a disposable device to be used in combination with a 10 mm diameter scope to prevent dimming and fogging of the lens.
The OptiDOCK Tissue Ligator is a disposable device intended to pass an absorbable suture loop during endoscopic procedures.

Description

The MedChannel OptiCLEAN Lens Irrigator is a single lumen endoscopic lens irrigator, designed for attachment to 10 mm diameter endoscopes. The irrigator comes in two sizes 285 mm or 305 mm, depending on surgeon's preference. The lens irrigator provides irrigation to the lens of an endoscope to prevent dimming and fogging of the lens during endoscopic surgical procedures.

The MedChannel OptiDOCK Tissue Ligator is a single use disposable suture passer, designed for use during endoscopic procedures. The OptiDOCK Tissue Ligator is pre loaded with PGA suture (USP 2-0).

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Summary of Standards Achieved

FDA Quality Systems Regulation 21 CFR § 820
ISO 10993:1 Biological evaluation of medical devices -- Part 1: Evaluation and testing
AAMI 11137 Sterilization of health care products - Requirements for validation and routine control -- radiation sterilization
AAMI 11135 Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization
USP 26 Absorbable Surgical Sutures
USP26, 861 Sutures - Diameter

Summary

In summary, the MedChannel Endoscopic Accessories are substantially equivalent to legally marketed devices. Quality System Controls assure the device is substantially equivalent to the predicate devices with respect to its performance, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

Mr. Frederick Tobia
Regulatory Consultant
MedChannel, LLC
75 Federal Street, 9th Floor
Boston, Massachusetts 02210

Re: K051700
Trade/Device Name: OptiCLEAN Lens Irrigator & OptiDOCK Tissue Ligator
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly (glycolide/L-lactide) surgical suture
Regulatory Class: II
Product Code: FEB, GAM
Dated: June 10, 2005
Received: June 24, 2005

Dear Mr. Tobia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Bucholz
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051700

Indications for Use

510(k) Number (if known): K051700

Device Name: MedChannel Endoscopic Accessories

Indications For Use:

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The OptiDOCK Tissue Ligator is a disposable device intended to pass an absorbable suture loop during endoscopic procedures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucchi MD for Melhexson

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K051700